Exhibit C

December 12, 2019

Opsens Inc
℅ Chris Henza
Regulatory Consultant
Ultra LifeScience Inc.
872 S. Milwaukee Avenue #286
Libertyville, Illinois 60048

Re: K192340
Trade/Device Name: OptoMonitor
Regulation Number: 21 CFR 870.2870
Regulation Name: Catheter Tip Pressure Transducer
Regulatory Class: Class II
Product Code: DXO
Dated: November 8, 2019
Received: November 12, 2019

Dear Chris Henza:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192340

Device Name
OptoMonitor

Indications for Use *(Describe)*

To measure pressure in bood vessels including both coronary and peripheral vessels, during diagnostic angiography and/or any interventional procedures.

Blood pressure measurements provide hemodynamic information, such as fractional flow reserve, for the diagnosis and treatment of blood vessels.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5 510(K) SUMMARY

5.1 SUBMITTER

Address: Opsens, Inc.

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Quebec (Quebec) G1P 4S3

Phone: 418-781-0333

Fax Number: 418-781-0024

Contact Person: Marc Chaunet, Director of Regulatory Affairs, Opsens Inc.

Email: marc.chaunet@opsens.com

Date Prepared: August 23, 2019

5.2 DEVICE

Name of Device: OptoMonitor

Common or Usual Name: Pressure Monitor

Classification name: Transducer, pressure, catheter tip (870.2870)

Regulatory Class: II

Product Code: DXO

5.3 PREDICATE DEVICE

OptoMonitor System cleared via K142598 (cleared on 06/12/2015).

5.4 REFERENCE DEVICE

The dPR index calculation algorithm software upgrade subject to this submission is substantially equivalent to the reference device, Volcano iFR Modality cleared under K173860, cleared on 04/11/2018 for similar intended use.

5.5 DEVICE DESCRIPTION

The proposed OptoMonitor is a software upgrade that includes software modifications allowing for the calculation of dPR index, and revised labeling relevant to this change. This device and its components are considered accessories to catheter pressure transducers and are intended for use with legally marketed catheters.

Software Description

The OptoMonitor with the new dPR calculation is an upgraded version of the software embedded in the previously cleared OptoMonitor's Display Unit. The OptoMonitor comprises the exact same hardware as cleared version with most of the software remaining unchanged, except for the display unit software which in addition to the current calculation of Fractional Flow Reserve (FFR), the upgraded version will also calculate the diastolic pressure ratio (dPR).

dPR is a resting index which consists in calculating the ratio of Pd and Pa over the diastolic portion of the heart beat cycle. dPR is a resting index for the diagnostic of the severity of stenosis equivalent to iFR (instantaneous wave-Free Ratio). iFR calculates the ratio of Pd and Pa over 75% of the diastolic portion.

The accuracy, specificity and sensitivity of dPR compared to iFR as a reference standard[1], using the same cut-off value of 0.89 and calculated from both CONTRAST[2] and VERIFY 2[3] studies, are 97.1% [95.7%, 98.1% @95%CI], 95.9% [93.6%, 97.5% @95%CI] and 98.4 [96.6%, 99.3% @95%CI] respectively.

The diagnostic performance of dPR (cut-off=0.89) vs FFR (cut-off=0.80) compared to iFR (cut-off=0.89) vs FFR (cut-off=0.80) was also assessed. It was demonstrated that the diagnostic performance of dPR vs FFR is not statistically different from the diagnostic performance of iFR vs FFR, with 95% confidence interval significantly overlapping.

Hardware Description

The OptoMonitor is composed of 3 parts: The Hybrid Cable Unit (HCU), the Signal Conditioner Unit (SCU) and the Display Unit (DU). There are no changes to the device hardware (HCU and SCU) from device system cleared under K142598. The device is a non-sterile, non-patient contact device.

5.6 INDICATIONS FOR USE

To measure pressure in blood vessels including both coronary and peripheral vessels, during diagnostic angiography and/or any interventional procedures.

Blood pressure measurements provide hemodynamic information, such as fractional flow reserve, for the diagnosis and treatment of blood vessel disease.

5.7 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed OptoMonitor with dPR software upgrade is substantially equivalent to the OptoMonitor System (K142598 cleared on 06/12/2015), the catheter (pressure guidewire) from the predicate device is not affected by this submission. The OptoMonitor Optical Unit (SCU), the Handle Unit (HU) and accessories (cables, power supply, etc) are not affected by this submission. The only change is a software

[1] An iFR cut-point of 0.89 matches best with an FFR ischemic cut-point of 0.80 with a specificity of 87.8% and sensitivity of 73.0%. (From ADVISE II and iFR Operator's Manual 505-0101.23)
[2] Nils P. Johnson et al., "Continuum of Vasodilator Stress From Rest to Contrast Medium to Adenosine Hyperemia for Fractional Flow Reserve Assessment", JACC : Cardiovalsular Interventions, Vol. 9, No. 8, 2016.
[3] Hennigan B. et al., "The VERIFY 2 Study (A Comparative Study of Resting Coronary Pressure Gradient,Instantaneous Wave-Free Ratio and Fractional Flow Reserve in an UnselectedPopulation Referred for Invasive Angiography)", Circ Cardiovasc Interv. 2016 Nov;9(11)

upgrade to the Display Unit (DU) and updated labeling (updated OptoMonitor Instructions for Use) to describe the additional software features. The proposed device and the predicate device are considered accessories to catheter pressure transducers and are coded as DXO.

Indications for the device remain unchanged from the predicate device.

The change does not impact the fundamental scientific technology of the OptoMonitor device. The change does not include modifications to the device's operating principle(s) or mechanism of action. The technological characteristics of the software upgrade raise a question concerning whether its performance can be expected to be equivalent to predicate device or completive products. Performance testing has confirmed equivalence. No new questions of safety and effectiveness were identified during review of Risk Management documentation or execution of Verification and Validation activities.

The identified questions of safety and efficacy apply to both the new device and the predicate and so the new device does not raise different questions of safety and efficacy. Therefore, the proposed device, OptoMonitor with dPR software upgrade, meets substantial equivalence requirements with regards to the legally marketed predicate OptoMonitor System (K142598 cleared on 06/12/2015) and reference devices, Volcano iFR Modality (K173860 cleared on 04/11/2018).

5.8 PERFORMANCE DATA

The risk management process has been used to evaluate the dPR software update to the OptoMonitor System in accordance with the guidelines set forth in ISO 14971:2007, Medical Devices – Application of Risk Management to Medical Devices. The risk analysis for the OptoMonitor with dPR has taken into consideration the medical device vigilance data of predicate device and OptoMonitor product experience. All residual risks that relate to the software update to include dPR have been taken into consideration while reviewing the risks. All OptoMonitor residual risks are outweighed by potential benefits and, therefore, are acceptable.

Software verification and validation testing were conducted in accordance with IEC 62304 and documented as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

No new questions of safety and effectiveness were identified during review of Risk Management documentation or execution of Verification and Validation activities.

No animal studies or clinical investigations are included with this submission.

5.9 CONCLUSIONS

The results from these tests mentioned above demonstrate that the technological and performance characteristics of the proposed OptoMonitor is comparable to the predicate device, support the safety and effectiveness of the device that is the subject of this 510(k), and ensure the subject device can perform in a manner equivalent to the predicate device with the same intended use.

The results of the verification/validation tests and the risk analysis have demonstrated that the software upgrade to allow calculation of dPR does not add any new questions of safety and efficacy and is therefore

substantially equivalent to the predicate OptoMonitor System (K142598 cleared on 06/12/2015) and reference devices, Volcano iFR Modality (K173860 cleared on 04/11/2018).

5.10 SUBSTANTIAL EQUIVALENCE

The new proposed device is the Opsens OptoMonitor including a new dPR modality. The predicate device is the currently marketed OptoMonitor (K142598 cleared on 06/12/2015) excluding the dPR modality. The OptoMonitor Optical Unit (SCU), the Handle Unit (HU) and accessories (cables, power supply, etc) are not affected by this submission. The only change is a software upgrade to the Display Unit (DU) calculating the new dPR index and an update to labeling (updated OptoMonitor Instructions for Use) to describe the additional software features. The OptoWire pressure guidewire that connects to the OptoMonitor is not affected by this submission. The reference device is the marketed Volcano s5 system (K173860), more specifically the iFR modality. The purpose of the reference device iFR modality is to demonstrate safety and effectiveness of the dPR modality.

Equivalence of Intended Use:

Indications for the device remain unchanged from the predicate device. The reference device contains similar indications for the pressure measurement modality.

Equivalence of Technological Characteristics:

The only difference between the proposed device and predicate is the addition of the dPR modality embedded into the software of the display unit. Technological Characteristics are herein identical between the proposed device and the predicate. dPR and iFR are resting indices used for the diagnostic of the severity of stenosis with the patient in resting condition, as opposed to inducing hyperemia when measuring FFR. dPR modality consists in calculating the ratio of Pd and Pa over the whole diastolic portion of the heart beat cycle while iFR calculate the same ratio over 75% of the diastole. Performance testing has confirmed equivalence of the proposed device to iFR (reference device). No new questions of safety and effectiveness were identified during review of Risk Management documentation or execution of Verification and Validation activities.

Safety and Effectiveness:

The identified questions of safety and efficacy apply to both the new device and the predicate and so the new device does not raise different questions of safety and efficacy. Specifically, a resting index calculation poses *less* risk to the patient as there is no need to use a hyperemic agent. The proposed device does not raise any different questions of safety and efficacy.

Conclusion

The proposed device, OptoMonitor with dPR software upgrade, was shown to be substantially equivalent to the legally marketed predicate OptoMonitor System (K142598 cleared on 06/12/2015), except for a software change that now includes a new dPR modality.

The safety and effectiveness of Opsens dPR modality has been shown to be substantially equivalent to the iFR modality of marketed device K173860 cleared on April 11, 2018.

		Proposed Device	**Predicate Device (Primary)**	**Reference Device**
Regulatory Information	Name	OptoMonitor	OptoMonitor	Volcano s5/s5i/CORE/CORE Mobile Precision Guided Therapy System
	510(k)#	K182126	K142598	K173860
	Predicates	K142598	K111395 K041134	K133323 K170133

		Proposed Device	Predicate Device (Primary)	Reference Device
	Product Code	DXO	DQX, DXO	IYO
	Class	2	2	2
	Regulation Number	870.2870	870.1330, 870.2870	892.1560
	Regulation Generic Name	Transducer, pressure, catheter tip	Wire, guide, catheter; Transducer, pressure, catheter tip	Ultrasonic Pulsed Echo Imaging System
Indications for Use	Indications for Use	To measure pressure in blood vessels including both coronary and peripheral vessels, during diagnostic angiography and/or any interventional procedures. Blood pressure measurements provide hemodynamic information, such as fractional flow reserve, for the diagnosis and treatment of blood vessel disease.	To measure pressure in blood vessels including both coronary and peripheral vessels, during diagnostic angiography and/or any interventional procedures. Blood pressure measurements provide hemodynamic information, such as fractional flow reserve, for the diagnosis and treatment of blood vessel disease.	The FFR v2.5 Modality of the s5/s5i/Core and Core Mobile Precision Guided Therapy System is indicated in all blood vessels, including coronary and peripheral arteries, to measure intravascular blood pressure during diagnostic angiography and/or interventional procedures. The iFR Modality is intended to be used in conjunction with currently marketed Volcano Pressure wires. In the coronary anatomy, the iFR modality has a diagnostic cut-point of 0.89 which represents ischemic threshold and can reliably guide revascularization decisions during diagnostic catheterization procedure. When used as for a pullback assessment, the iFR modality is intended as a visual aid in decision making by indicating the relative location and severity of the stenosis such as, multiple lesions or diffuse disease. Additional, unrelated indications for use
Technological Characteristics	Prescription Use	Rx Only	Rx Only	Rx Only
	System Components	Reusable signal processor/monitor; Embedded software; Connecting Cables	Reusable signal processor/monitor; Embedded software; Connecting Cables. Sterile disposable guide wire.	Reusable signal processor/monitor; Embedded software; Connecting Cables.
	System Capabilities	Measurement of intravascular blood pressure.	Measurement of intravascular blood pressure.	Measurement of intravascular blood pressure. Additional, unrelated functions
	Pressure Sensing & Signal Transmission Technology	Senses pressure from Fiberoptic sensor.	Fiberoptic sensor & fiber bundle embedded in guidewire. Senses pressure from Fiberoptic sensor.	Pressure measurement is captured through the use of pressure wires.
	Connected devices	OptoWire	OptoWire	SmartWire II, PrimeWire Prestige, PrimeWire Prestige Plus, Verrata, Verrata Plus
	Auto-zeroing	Yes	Yes	Yes.
	Real Time Curves	Aortic instantaneous pressure, aortic mean pressure, distal instantaneous	Aortic instantaneous pressure, aortic mean pressure, distal	Aortic instantaneous pressure, aortic mean pressure, distal instantaneous pressure, distal mean pressure

		Proposed Device	Predicate Device (Primary)	Reference Device
		pressure, distal mean pressure	instantaneous pressure, distal mean pressure	Heart rate
	Real Time Numerical Values	Mean aortic pressure, mean distal pressure, mean Pd/mean Pa, , dPR	Mean aortic pressure, mean distal pressure, mean Pd/mean Pa	Mean aortic pressure, mean distal pressure, mean Pd/mean Pa, iFR
	Recording Values	Instantaneous Pa, Pd and Pd/Pa; mean Pa; mean Pd; mean Pd/mean Pa	Instantaneous Pa, Pd and Pd/Pa; mean Pa; mean Pd; mean Pd/mean Pa	Instantaneous Pa, Pd and Pd/Pa; mean Pa; mean Pd; mean Pd/mean Pa
	Hyperemic agent	Not required for dPR Required for FFR	Required for FFR	Requiered for FFR. Not required for iFR
	Calculation types	dPR, FFR	FFR	FFR, iFR
	Diastolic Resting Indices calculations	$dPR = \frac{P_{d,diastole}}{P_{a,diastole}}$	N/A	$iFR = \frac{P_{d,WFP}}{P_{a,WFP}}$
	Resting Indices Wave selection	Automatically selected	N/A	Automatically selected
	Resting indices cutoff point	.89	N/A	.89
	Aortic Input	High Level (100 mmHg/V)	High Level (100 mmHg/V)	High Level (100 mmHg/V)
	Distal pressure output	Low level 5uV/mmHg	Low level 5uV/mmHg	Low level 5uV/mmHg
	Hardware components	Signal Conditioner Unit (SCU), the Display Unit (DU), The Handle Unit (HU) and accessories (cables, power supply, etc)	Signal Conditioner Unit (SCU), the Display Unit (DU), The Handle Unit (HU) and accessories (cables, power supply, etc)	The reference device is a larger system with additional capabilities not related to this submission.
	Operating Pressure	70 to 106 kPa	70 to 106 kPa	70 to 106 kPa
	Pressure Range	-30 to 300 mmHg	-30 to 300 mmHg	-30 to 300 mmHg
	Pressure Accuracy	+/- 1 mmHg plus +/- 1% of reading (pressure range -30 to 50 mmHg) or +/- 3% of reading (pressure range 50 to 300 mmHg)	+/- 1 mmHg plus +/- 1% of reading (pressure range -30 to 50 mmHg) or +/- 3% of reading (pressure range 50 to 300 mmHg)	Not specified.
	Thermal Zero Shift	<0.3 mmHg/deg C	<0.3 mmHg/deg C	Not specified
	Zero Drift	<1 mmHg/h	<1 mmHg/h	5 mmHg / 10 minutes
	Electrical Isolation	class 1 (functional ground)	class 1 (functional ground)	class 1 (functional ground)
	User Interface	Touchscreen	Touchscreen	Bedside : Touchpad or joystick Control room : Console